K051419

510(k) Summary

21CFR § 807.92

APR 27 2006

Submitter: *Inditherm Medical*
Houndhill Park
Bolton Road
Rotherham S63 7LG
United Kingdom

Contact: *Nick Bettles, Division Director - Medical*

Date Prepared: *1 June, 2005*

Trade Name: Inditherm Patient Warming System
Model numbers: MECU1, OTM1, OTM2, GTM1, PTM1, OTB, RB1

Common Name: *Thermal Regulating System*

Equivalence to: *Klimamed Thermal Mat and Controller (K011859)*
Klimamed Thermal Blanket and Controller (K031728)

Description: *The Inditherm Patient Warming System consists of a precision temperature control unit that controls and monitors the temperature of a mattress or blanket composed of a carbon polymer material. A pressure relief pad is integrated into the mattress, underneath the flexible warming surface.*

Intended Use: *Designed for use in the operating room, recovery room, anesthetic room, intensive care, medical and surgical floors, patient transport and emergency department; the Inditherm Patient Warming System provides safe and controlled warming to assist patients to maintain normal body temperature. In addition to providing warming and control, the mattress also provides pressure relief to help prevent pressure sores.*

Technological Characteristics: *Comparisons between the new and predicate devices shows that technological characteristics (i.e. device design, materials, components, and dimensions) and indications for use for the Inditherm Patient Warming System are equivalent to the currently marketed predicate devices.*

Non-Clinical Data: *The Inditherm Patient Warming System complies with the following performance standards:*

Standard	Description
BS EN 60601-1:1990	Medical Electrical Equipment – Part 1: General Requirements for Safety
BS EN 60601-2-35:1997	Medical Electrical Equipment – Part 2: Particular Requirements for the safety of blankets, pads and mattresses, intended for heating in medical use.
MDD: 93/42/EEC	Medical Device Directive (MDD)

Clinical Data: *The Inditherm Patient Warming System has been in clinical use since 1999 in Europe. No additional clinical testing was required.*

Conclusion: *The Inditherm Patient Warming System was found to be equivalent to technological characteristics and indications for use for the predicate device(s).*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2006

Inditherm Medical
c/o M.W. (Andy) Anderson, Ph.D.
Senior Regulatory Project Director
Regulatory and Clinical Research Institute, Inc.
5353 Wayzata Boulevard, Suite 505
Minneapolis, MN 55416

Re: K051419
Patient Warming Systems Model Numbers: MECU1, OTM1, OTM2, GTM1, PTM1, OTB, RB1
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (Two)
Product Code: DWJ
Dated: April 20, 2006
Received: April 21, 2006

Dear Dr. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can

be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: **K0501419**

Device Name: ***Inditherm Patient Warming System***

Indications for Use:

Designed for use in the operating room, recovery room, anesthetic room, intensive care, medical and surgical floors, patient transport and emergency department, the Inditherm Patient Warming System provides safe and controlled warming to assist patients to maintain normal body temperature. The mattress includes a pressure-relieving pad.

Prescription Use ____X____ OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – (CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lachman
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K0501419